TERUMO CARDIOVASCULAR GROUP

TITLE: Supplier Questionnaire Request

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| **Company Name**      | **Supplier Contact:**  | **Name**      | **Title**      |
| **Company Website**       | **Email**      | **Phone**      |
| **Manufacturing/Service Location** | **Other facilities used by Terumo CVG? (e.g. shipping)** | **Remit**[ ]  **N/A** |
| **Street Address**      **City, State**      **Postal Code, Country**      **Phone**       | Yes [ ]  No [ ]  If yes, please explain:      | **Street Address**      **City, State**      **Postal Code, Country**      **Phone**       |
| How long in operation?       | Total number of employees at this site?       |
| Number in Quality:       Manufacturing:       Engineering:       Temporary:       |
| Is your company registered with the FDA?        | FDA registration number, if applicable       |
| Percentage of customers in medical device industry?       | Size of Facility in square feet:       |
| Scope and overall summary of primary products / services provided at this facility:      | Does your company have a quality policy? Yes [ ]  No [ ] If yes, please state or attach policy      |
| Does your company rely on third party contract manufacturers?  | Yes [ ]  No [ ]  N/A [ ]  If yes, please explain:      |
| Does your company provide sterilization services or contract a 3rd party sterilization service provider? | Yes [ ]  No [ ]  N/A [ ]  If yes, please explain:      |
| Does your company rely on third party design/engineering providers? | Yes [ ]  No [ ]  N/A [ ]  If yes, please explain:      |
| Does your facility have a clean room with established environmental controls? | Yes [ ]  No [ ]  N/A [ ]  If yes, please explain:      |

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| **#** | **Question** | **Scale Rating** |
| **Established:** Defined, documented (in writing or electronically), and implemented | **Informal System:**May have procedure but not documented or may be documented but no formal procedure exists | **Not Established:**Process is not defined, documented (in writing or electronically), and implemented |
| **1** | Does your company’s Quality Management System (QMS) currently meet national or international standards (i.e. ISO 9001)? | [ ]  5: QMS is certified to ISO standard | [ ]  3: QMS exist but not certified to ISO standard | [ ]  1: No documented QMS |
| **2** | Does your company have a Quality Manual that describes the systems and controls to assure the quality of its products and/or services? | [ ]  5: Quality Manual established  | [ ]  3: Quality Manual documented but not rev controlled | [ ]  1: No Quality Manual established |
| **3** | Does your company have a Contract Review Policy/Procedure? | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists  | [ ]  1: No Policy/ Procedure established |
| **4** | Does your company utilize a documented engineering change control system (EC/ECO) Policy/Procedure? | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **5** | Does your company have a Document and Quality Records Control and Retention Policy/Procedure? | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **6** | Does your company have a Purchasing Policy/Procedure that includes requirements for maintaining an Approved Supplier List (ASL) for product and service providers with product and/or quality system impact? | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **7** | Does your company use Good Documentation Practices (GDP’s)?  | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **8** | Does your company utilize controlled travelers, work orders, bill of materials, or job routers? | [ ]  5: Documentation established | [ ]  3: Informal system exists | [ ]  1: No documentation established |
| **9** | Does your company have an Identification and Traceability Policy/Procedure that can be utilized to determine date of manufacture/service and product/equipment status? | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **10** | Does your company have work instructions that are used to control manufacturing (or service) processes, inspection operations and product/equipment release testing?  | [ ]  5: Work Instructions established | [ ]  3: Informal process exists | [ ]  1: No Work Instructions established |
| **11** | Does your company have an Inspection and Testing Policy/Procedure? | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **12** | Does your company have a Training Policy/ Procedure? | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **13** | Does your company have Calibration Policy/Procedure? N/A [ ]  | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **14** | Does your company have a Control of Nonconforming Material/Product/Service (NCR) Policy/Procedure?  | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **15** | Does your company have a Corrective and Preventive Action (CAPA) and Complaint Handling Policy/Procedure? | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **16** | Does your company have a Handling, Storage, Packaging, and Delivery Policy/Procedure? N/A [ ]  | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **17** | Does your company have a Statistical Techniques and Sampling Plan Policy/Procedure? N/A [ ]  | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **18** | Does your company have a Process Validation Policy/Procedure? N/A [ ]  | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **19** | Does your company have a Risk Management Policy/Procedure? | [ ]  5: Policy/ Procedure established | [ ]  3: Informal system exists | [ ]  1: No Policy/ Procedure established |
| **20** | Does your company have an independent quality organization/department? | [ ]  5: Independent Quality Department  | [ ]  3: Quality Department is not independent | [ ]  1: No Quality Department |

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| **Supplier Questionnaire Completion** *(To be completed by Supplier)* |
| **Supplier’s Representative** | Sign:  | Print:       |
| Date:       | Title:       |
| **Questionnaire Return Instructions***Please return completed Supplier Questionnaire Request via e-mail***E-mail:**  Attn: Supplier Quality Engineering TCVSELW.SQE@terumomedical.com |

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| **Questionnaire Evaluation** *(To be Completed by TCVG)* |
| Supplier Total Scale Rating (Total Points Questions 1 – 20):       |
| This Supplier Questionnaire was reviewed and responses are: (check one)[ ]  Acceptable [ ]  Not Acceptable**Comments:**       |

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| **Approvals** |
| **Supplier Quality Engineer (or Designate)** | **Print**      | **Title**      | **Signature** | **Date**      |
| **Supplier Quality Engineering Management** | **Print**      | **Title**      | **Signature** | **Date**      |